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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,336	07/18/2003	Patrick W. Truitt	011579US3	3290

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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02/24/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/623,336

Applicant(s)

TRUITT ET AL.

Examiner

ANNETTE F. DIXON

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9,11-15,24,31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,9,11-15,24,31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response the request for continued examination filed on January 20, 2011. Examiner acknowledges claims 8, 9, 11-15, 24, 31, and 33-35 are pending, with claims 8, 9, 11-15, 24, and 31 having been currently amended, claims 34 and 35 having been newly added, and claims 1-7, 10, 16-23, 25-30, and 32 having been cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 20, 2011 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8, 9, 11-15, 24, 31, and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, independent claims 8, 24, and 31 now recite “a pressure within a standard deviation of no more than 1.5 c cmH₂O of the preselected pressure without feedback control of the pressure generator”; however, the originally filed disclosure does not provided enablement to how the aforementioned functionality is preformed. In fact, the original specification of the instant invention discloses only the “standard deviation from a selected pressure” (Pages 15 and 16, Paragraph 39) absent of any disclosure or teachings as to how the standard deviation is calculated without feedback control. Examiner is unsure if there needs to be a specific element(s) in order to perform the calculation, such as a pressure gauge or a sensor and additionally who performs the functionality of calculating the standard deviation. As there is specific recitation or support for the features of “a pressure within a standard deviation of no more than 1.5 cmH₂O of the preselected pressure without feedback control of the pressure generator” is performed are lacking in the original disclosure as filed, the subject matter added to the claims is considered to lack enablement and must be cancelled from the claims. Dependent claims 9, 11-15, and 33-35 incorporate the subject matter lacking enablement from which they depend. For purposes of this rejection, Examiner has presumed the calculation of the "standard deviation...without feedback control" can be explicitly or implicitly performed by a health care professional in the determination of specific ventilation parameters based on the needs of the patient; where the standard

deviation is desired to be minimal in order to prevent situations of overpressure or deprivation of oxygen to a patient. However, appropriate correction and clarification is required without introducing new matter into the disclosure of the application.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (5,452,714) in view of DeVries et al. (5,868,133).

As to Claims 31 and 33, Anderson discloses a method and apparatus for supplying gas, comprising: a source of breathing gas (via compressor 250 in compressor subsystem 24), a pressure generator (compressor 250 in compressor subsystem 24), and a patient circuit (52) for supplying the pressurized gas to the patient. Anderson discloses the control of the ventilator's operating parameters is by control knob (296) which is operated by a health care professional to select the desired ventilation parameters by fine control (Column 14, Lines 43-50) in order to prevent deprived or over pressurization of air (Column 7, Lines 59-65) and this control is an open loop system ("not feedback", Column 8, Line 3) for the opening a closing of valves to change ventilation parameters. (Column 3, Line 65 thru Column 4, Line 6, and Column 7, Line 45 thru Column 8, Line 8). Yet Anderson does not expressly disclose

the standard deviation, nor the desired ventilation parameters with respect to the specifics of the pressure generator. Regarding the standard deviation limitation, please see the rejection under 35 U.S.C. 112, first paragraph, in light of the relationship between Anderson's user controls and the ability to select desired ventilation parameters; where the standard deviation is desired to be minimal in order to prevent situations of overpressure or deprivation of oxygen to a patient, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a standard deviation with respect to the user controls, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Moreover, Applicant has not asserted that the specific standard deviation recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing a fine measurement of the ventilation parameters for the patient; thus the use of the specific standard deviation lacks criticality in its design.

Consequently, one of ordinary skill in the art would have expected Applicant's ventilator to perform equally well with the modified Anderson. Regarding the desired ventilation parameters with respect to the specifics of the pressure generator, DeVries teaches pressure generating ranges of airflow 10-140 liters per minute (Column 10, Lines 47 and 48) and a pressure flow 1 to 60 centimeters of water (Column 11, Lines 29 and 30) where the pressure generator (compressor 30) has a motor (102), a rotatable drive shaft (114) and an impeller (104) for the purpose of providing inspiratory gas flow to a patient (Column 8, Lines 16-23 and Column 17, Lines 20-39). Therefore, it would have

been obvious to one having ordinary skill in the art to modify the controls of the ventilator, a known result effective variable, in order to provide a fine measurement of the ventilation parameters for the patient and to modify the pressure generator of Anderson, to include the specifics and explicit ventilation pressures and flows, as taught by DeVries in order to provide inspiratory gas flow to a patient.

7. Claims 8, 9, 11, 13-15, 24, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (5,452,714) in view of DeVries et al. (5,868,133), as applied to claim 31 and further in view of Blair (4,653,976).

As to Claims 8, 11, 13-15, and 24, please see the rejection of claim 31, the difference between claim 31 and claims 8 and 24 are the incorporation of explicit “plurality of impeller” features. Blair teaches an impeller (Figure 2) having a first set of impeller blades (38) and a second set of impeller blades (40) which are partial blades of the first larger set of impeller blades (38) for the purpose of preventing excessive diffusion of the gas flow as the air channels increase in size with the increasing impeller circumference from the air inlet to the exit. (Column 3, Lines 25-30). Additionally Blair teaches the impeller blades are about a hub (27), having leading edges adjacent to the hub (27) and trailing edges at the perimeter of the impeller (40), where the impeller blades are shorter near the trailing edge. Therefore, it would have been obvious to one having ordinary skill in the art to modify the modified Anderson to include the specifics of the impeller features as taught by Blair to prevent excessive diffusion of the gas flow

as the air channels increase in size with the increasing impeller circumference from the air inlet to the exit.

As to Claims 9 and 34, the modified Anderson discloses an impeller having first full and second partial sets of impeller blades; yet, does not expressly disclose the midpoint of the first full set of impeller blades to be the start of the second partial set of impeller blades for the purpose of preventing excessive diffusion (Blair: Figure 2, Column 3, Lines 25-30) In light of the relationship between the impeller blades and the ability to prevent excessive diffusion, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate location with respect desired level of diffusion prevention, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Moreover, Applicant has not asserted the specific location of the second partial set of impeller blades at the midpoint of the first full set of impeller blades recited provides a particular advantage, solves a stated problem or serves a purpose different from that of preventing excessive diffusion, thus the use of the specific location lacks criticality in its design. Consequently, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the modified Anderson. Therefore, it would have been obvious to one having ordinary skill in the art to modify the location of the second partial set of impeller blades of the modified Anderson a known result effective variable in order to provide a location of the second partial set of impeller blades capable of preventing the desired amount of diffusion in the gas profile.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (5,452,714) in view of DeVries et al. (5,868,133) and Blair (4,653,976), as applied to claim 8 and further in view of Wassmann (3,751,179).

As to Claim 12, the modified Anderson, specifically Blair, discloses the hub (27) for a radial impeller; yet does not expressly disclose the shape of the hub having a smooth outer surface that curves radially outlet toward the plurality of inlets. Wassmann teaches the hub (42) having a curved shape (40) attached thereto prior to the plurality of impeller blades for the purpose of providing a central structure by which the drive shaft and bearing sealing structure is attached to the impeller blades of the pump. (Column 2, Lines 60-67). In light of the relationship between the shape of the hub and the ability to receive the drive shaft for the impeller blades, it would have been an obvious matter of design choice to make the different portions of the hub of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the hub of the modified Anderson to include a curved shape as taught by Wassmann as a shape that can effectively support the bearing and sealing structure of the impeller blades on to the drive shaft.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (5,452,714) in view of DeVries et al. (5,868,133) and Blair (4,653,976), as applied to claim 24 and further in view of Parisi et al. (6,224,335).

As to Claim 35, please see the rejection of claim 24, where the difference between 24 and 35 is the incorporation of a skirt on the impeller. Parisi teaches the use of a skirt (16) extending downwardly from the second face of an impeller (10) to provide a location by which the fan can be balanced thereby helping with stiffening the fan. (Column 3, Lines 25-30). Therefore, it would have been obvious to one of ordinary skill in the art to modify the impeller blades of the impeller of Pauly to include a downwardly extending region of a skirt, as taught by Parisi for the purpose of stiffening the fan and providing a structure to balance weights.

Response to Arguments

10. Applicant's arguments with respect to claims 8, 9, 11-15, 24, 31, and 33-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNETTE F. DIXON whose telephone number is (571)272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

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